

**YEAR 2 CLINIC VISIT****TABLE OF CONTENTS**

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## YEAR 2 CLINIC VISIT

### 1. Overview of Measurements

Health ABC participants who attend the year 2 clinic visit will have the following measurements unless specifically excluded according to criteria described in each chapter:

- Questionnaire
- Food frequency
- Review of medications used in the past two weeks (Medication Inventory Form)
- Physical measurements, including blood pressure, radial pulse, temperature, and weight
- Grip and quadriceps (Kin-Com) strength testing
- 20-meter walk
- Long distance corridor walk
- Dental examination
- Periodontal assessment
- Bone mineral density and body composition by DXA
- Bone ultrasound heel assessment
- Serum and cells for laboratory testing, and serum and urine specimens to be frozen and archived
- MRI (off site) of knee for participants with knee osteoarthritis and controls
- X-ray (off site) of knee for participants with knee osteoarthritis and controls
- Energy Expenditure (done on random sample of participants)

After the completion of each component of the Health ABC Year 2 Clinic Visit, the Procedure Checklist should be checked (see Appendix 1

**Scripts in Protocols and Worksheets**

It is very important that examiners read the Health ABC operations manual protocols. Scripts are included in the operations manual in order to standardize the administration of the many tests given to participants in the study. These scripts clearly identify key points that are important to convey to the participant. A number of worksheets also include script. Examiners are encouraged to memorize the standardized script that appears in the protocols and/or worksheets, but they are free to adapt the script to their own words, when appropriate, as long as the same information is conveyed to the participants and is presented in the same order as the standardized script.

**2. Working with Older Participants**

Participants in our research studies are NOT patients; they are very valued volunteers who deserve to interact with study staff who are always at their best. The participants are people who are willing, for very little in return, to contribute their time, energy, and honesty about their situations in the hope of making a difference. We need to do everything we can to make their time with us an enjoyable experience. Remember, in order for Health ABC to be successful, we need participants to agree to return for the next 6 years after their baseline visit. If they do not feel that they were treated with respect, we may lose them for follow-up. Time spent in making their visit as pleasant as possible is time well spent.

Research participants are free to refuse to have any test completed and/or to answer any questions that we ask. Because people that volunteer for studies tend to be generous people, refusals rarely happen. When they do occur, it is often because they do not understand what is being asked of them or why it is being requested. Take the time to explain. However, if they still refuse, respect this decision as their absolute right and move to another activity or question.

It is imperative that we always treat each research participant with respect. This involves, but is not limited to, providing the necessary information to prepare them for their visit, greeting them warmly as they arrive in clinic, thanking them for their participation before the exams are started, answering any questions that they may have, explaining available test results at the end of the visit, thanking them again for their time and interest at the end of the visit, and not wasting their time by making them wait for long periods unnecessarily.

Dealing successfully with older research participants requires that we be sensitive to their potential needs and concerns. These needs may be related to ambulation difficulties, hearing and sight difficulties, discomforts associated with completing the clinic visit (e.g., long periods of fasting without even a cup of coffee, difficult blood draws, fatigue due to their health status combined with a long visit, etc.), competing

personal difficulties (e.g., depression, an ill spouse, etc.), and the new experience of being a research participant.

We must also be aware that the information we collect as research data may identify a new medical problem that may need to be brought to the attention of a participant's primary care physician for follow-up. We, as a study staff, do not provide diagnosis or treatment. However, when participant consent has been obtained, we may need to notify appropriate parties (i.e., physicians, participants themselves, proxies, etc.) of a new abnormal finding. This should be accomplished by the clinic coordinator(s) after discussing the finding with the medical director/investigator.

Occasionally participants are wary of finding out that there is something "wrong" with them that they would rather not know. Tread lightly here! Participants have a right to have this information remain unreported to them or to their physicians/ family members, etc. Again, often their refusal is due to a lack of understanding and/or information. Take the time to discuss their fears. Contact the clinic coordinator to assist in the discussion as needed. However, participants do have the right to refuse to have information made known to themselves and/or others.

Keep in mind that, for the most part, participants who report feeling "fine" are "fine." Relax and enjoy your time with our Health ABC participants!

### **For Clinic Coordinators and Investigators:**

We have an obligation to communicate with our participants and/or their physicians when appropriate. Participants deserve to receive their test results in a timely fashion. These results should be reviewed by the clinic nurse coordinator/investigators prior to being sent to the participant and/or their physician. There should be no surprises when a participant receives their results in the mail. When possible, the clinic coordinator should discuss any abnormal findings with participants BEFORE the results are sent in the mail. Coordinators need to be sure that test results are complete and accurate; and these results must be sent out as quickly as possible. The participant report serves as an important thank-you for time spent participating in each Health ABC examination.

## **3. Preparation for the Year 2 Clinic Visit**

### **3.1 Participant Preparation**

Each participant who comes to the Health ABC Clinic Visit will have been told about the contents of the visit during the phone conversation to set up the clinic visit. We recommend reminder phone calls or postcards prior to the visit to re-emphasize the following:

- The participant should bring in all prescription and non prescription medications used in the preceding two weeks.
- Dietary guidelines (fasting) prior to the visit should be followed.
- Guidelines should be followed for footwear and undergarments for women
- A urine specimen will be collected shortly after they arrive at the clinic.

Please see an example of a reminder letter in Appendix 4.

### 3.2 Clinic Preparation

At the time of the year 2 clinic visit, the following should be available for each participant:

- A completed Pre-visit Screener for Knee X-ray form
- A Year 2 Questionnaire
- A Year 2 Clinic Visit Workbook labeled with the participant's name, acrostic, and Health ABC Enrollment ID Number. See Table 1 (below) for complete list of the forms contained in the Year 2 Clinic Visit Workbook.
- The participant's chart. Field centers should also keep "progress notes" in the participant's chart. Progress notes may be used to record staff comments and questions, and to document protocol problems and their resolution. Each entry should be dated and initialed by the staff person recording the note.

### 3.3 Assignment of Health ABC Enrollment ID Number

Each participant will be assigned an alphanumeric six-character Health ABC Enrollment ID number at the baseline clinic visit. The first two characters of this ID number are HA for Memphis and HB for Pittsburgh. The number that follows these two characters has four digits. The four-digit numbers assigned to Memphis participants will begin with the number 1000. The four-digit numbers assigned to Pittsburgh participants will begin with the number 5000. These four-digit numbers will be pre-printed on the workbook in the lower left-hand corner of the page. The examiner should transcribe, in the space provided at the top of the page, first HA or HB (depending on the field center) and then the four numbers that are pre-printed on the page.

Exception: The Resting ECG test will require that the first digits of the Health ABC number be “01” for Memphis and “02” for Pittsburgh, instead of HA and HB, respectively.

Table 1

**Forms Contained in the Health ABC Baseline Clinic Visit Workbook**

Baseline Clinic Visit Cover Sheet:	Side to Measure Assessment
HCFA ID#/HABC ID#; Arrival/Departure;	Isokinetic Strength (Kin-Com)
Physician Report Release	Bone Density (DXA) Scan
Baseline Clinic Visit Procedure Checklist	Thigh and Abdominal Circumference
ECG Tracking	Performance-Based Measures:
Phlebotomy	Chair Stands, Standing Balance, Balance Walks
Oral Glucose Tolerance	Long Distance Corridor Walk
Laboratory Processing	Teng Mini-Mental State
Medication Inventory	Digit Symbol Substitution
Standing & Sitting Height; Weight;	Grip Strength
Sagittal Diameter;	Finger Tapping Test
Blood Pressure	Pulmonary Function Test Tracking
Ankle-Arm Blood Pressure	CT Tracking
Pulse Wave Velocity Tracking	

#### 4. Clinic Flow and Measurements

##### 4.1 Overview of Clinic Flow

Two important features of the baseline clinic visit are the large number of measurements required and the need for certain exams to precede others. It is critical that each field center have a flow chart to guide clinic flow. In general, each field center will need to model clinic flow based on availability of rooms, certified staff, and other potential limitations. The following guidelines for the order of specific measurements are divided into mandatory, which must be followed, and preferable, which are highly recommended but may be modified without jeopardizing the measurements:

##### Mandatory

Height (seated and standing) and weight before PFT

Laboratory specimen collection (both blood and urine) before OGTT (In rare circumstances a participant may be unable to provide a urine specimen prior to the OGTT. Collect the urine sample later in the day. Record on the Phlebotomy Form, question 8 in the comment section that urine was collected after the glucola consumption. Very rarely, a participant will come back and provide a urine sample [after fasting] on another day within 1 to 2 weeks of their baseline clinic visit.)

ECG before OGTT

LDCW at least 20 minutes after OGTT

Preferable:

Finger tap before PFT

Kin-Com before thigh circumference

Please note: The Side to Measure Form should be used to determine which leg to measure for the Kin-Com, BMD Measurement, Thigh Circumference, and CT exams and should be completed before the first of these exams is done. For most participants all of these exams will be performed on the right leg. However, if the Kin-Com or BMD measurement is contraindicated on the right side and must be performed on the left, then all three measurements should be done on the left, if possible. In some cases, however, it will be necessary to perform the BMD and Kin-Com measurements on different sides. The thigh circumference should always be taken on the same side as the Kin-Com.

The Side to Measure Form is not an algorithm for determining which side, but should provide most of the information needed to make an educated guess as to which side will be used for each measurement. In some cases, the examiner will decide which side to measure based on information obtained during the testing. Thus, it is inevitable that it will not be possible to coordinate the measurement side in all cases.

#### **4.1.1 Resting ECG**

Resting ECG must be performed in the fasting state. It is critical that the procedure be done before the glucose load for the OGTT. The ECG Tracking Form in the Baseline Clinic Visit Workbook must be completed to record whether or not a successful test was obtained (and if not, what was the reason); whether or not hard copies were printed out with and without interpretation; and if there were any protocol deviations.

See Chapter 3A for detailed procedures.

#### **4.1.2 Oral Glucose Tolerance Test**

The Oral Glucose Tolerance Test Form in the Baseline Clinic Visit Workbook must be filled out to record information about the participant's diabetic status, whether or not the test was completed, the time of the test, whether or not the entire glucose drink was consumed, and the time of the blood draw. Occasionally, participants who qualify for the OGTT but who did not fast before their baseline clinic visit, will come back another day for this test. The Return Visit Oral Glucose Tolerance Test Form must be filled out to record the information listed above.

See Chapter 3C for detailed procedures.



### **4.1.3 Cognitive Function**

Cognitive function will be assessed by the Teng Mini-Mental State and the Digit Symbol Substitution examinations.

See Chapters 3Q and 3R for detailed procedures.

### **4.1.4 Medication Use**

Prescription and non-prescription medications used by participants in the two weeks prior to their baseline clinic visit will be recorded on the Medication Inventory Form (MIF) in the Baseline Clinic Visit Workbook.

See Chapter 3E for detailed procedures.

### **4.1.5 Anthropometry and Physical Measures**

A number of anthropometric and physical measurements will be made on all participants who attend the Baseline Clinic Visit. The measurement of height and weight comes early in the exam and offers a good opportunity to answer questions and promote goodwill towards the study.

See Chapters 3F, 3G, 3I, 3J, 3K, and 3N for detailed procedures.

### **4.1.6 Performance Tests**

The performance tests to be done at the Baseline Clinic Visit include the finger-tapping test, chair stand(s), standing balance (tandem stands and one-leg stand), and balance walks.

See Chapter 3O for detailed procedures.

### **4.1.7 Grip and Quadriceps (Kin-Com) Strength Testing**

Kin-Com testing should be performed on the same side as hip BMD, thigh circumference, and thigh CT (on the right in most cases). The Side to Measure Form in the Clinic Visit Workbook must be filled out before Kin-Com, thigh circumference, and bone mineral density tests (see section 4.1).

See Chapters 3S and 3L for detailed procedures.

#### **4.1.8 Long Distance Corridor Walk**

See Chapter 3P for detailed procedures.

#### **4.1.9 Pulmonary Function Testing**

Height and weight must be obtained prior to PFT testing. The Pulmonary Function Test Tracking Form in the Clinic Visit Workbook must be completed to obtain exclusion information, to record results, and to record whether or not the test was completed, and, if it was not completed, to record why.

See Chapter 3V for detailed procedures.

#### **4.1.10 BMD and Body Composition**

Bone mineral density of the hip and whole body will be performed using Hologic QDR 4500 and 1500 instruments. Body composition measurements are obtained during the whole body scan. BMD of the hip should be performed on the same side as Kin-Com strength measurements, thigh circumference, and thigh CT (on the right in most cases). Again, the Side to Measure Form should have already been filled out before this test is administered. Also, the Bone Density (DXA) Scan Form in the Baseline Clinic Visit Workbook must be completed to record information about exclusions, artifacts, recent tests that could potentially interfere with the scan, and whether or not a bone density measurement was obtained.

See Chapter 3M for detailed procedures.

#### **4.1.11 Pulse Wave Velocity**

See Chapter 3H for detailed procedures. A Pulse Wave Velocity Tracking Form is completed to record if there is a carotid bruit, how many examiners performed the test, whether or not the test was successful; and if the test was not successful, to record the reason(s).

#### **4.1.12 CT Scheduling, Directions**

The information in the header of the CT Tracking Form (except for Tech ID#) should be completed before the participant is transported to the CT facility. The form should accompany the participant to the facility. CT of the thigh includes both legs; the CT thigh length measurement should be performed on the same side as the Kin-Com measurement. The Kin-Com side (right leg; left leg) field on the Baseline Clinic Visit Procedure Checklist Form should be filled in before the participant is transported to the CT facility. The CT Tracking Form is filled out to record whether or not abdominal, thigh, and spine scans were obtained, and if they were not, to record the reason(s).

#### **4.2 Procedure Checklist and Exit Interview**

At the end the Baseline Clinic Visit, an exit interview should be performed to:

- Thank the participant. The Baseline Visit is long and can be tedious. Be sure the participant knows how much we appreciate their participation and patience.
- Answer questions. Some participants may have questions about various examinations.
- Confirm that all exams and measurements were completed. Review the Baseline Clinic Visit Workbook and complete the Procedure Checklist appropriately.
- Make sure the Baseline Clinic Visit Workbook cover sheet is completed; ie., the header information including the HCFA Screening ID # bubbles and the Health ABC Enrollment ID #; time of arrival; time of departure; status of the clinic visit (whether or not the visit was completed; whether the visit included the CT) and permission to send test results to the physician (see Appendix 2).
- Provide selected results (Appendix 3). Participants will be given the following results:
  - ^ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.
  - ^ Standing height. Height should be converted from mm to feet and inches for the participant.
  - ^ Weight. Weight in pounds should be provided.
  - ^ Spirometry. Age and height-adjusted percent of predicted FEV1 (forced expiratory volume), FVC (forced vital capacity), and FEV1/FVC ratio should be provided.

- ^ BMD and body composition. DXA results from the total hip should be provided as this site is the most reproducible and is used clinically. The participants BMD will be plotted by the DXA technician on a sex and race-specific normative curve. A brief explanation of these results will be included on this printout. Percent body fat will be given but no reference range will be provided.
- Tell participant that additional results and a summary will be sent to them within 8 weeks of their Baseline Clinic Visit. Determine if the participant would like their test results sent to their physician. Note consent for release of reports to physician (yes or no) on the Clinic Visit Procedure Checklist.
- Summarize future contact with the study both for scheduled visits and endpoints. Participants should be reminded to immediately contact the clinic for any of the following events:
  - ^ Hospitalization. Any overnight stay in an acute care facility.
  - ^ Surgery. Any surgery requiring regional (e.g., spinal) or generalized anesthesia. This includes same-day surgery that does not result in an overnight hospitalization.
  - ^ Fracture. Any broken bone, including minor fractures of the toes, fingers, etc.

Suggested script: “It is very important to the study for us to know as soon as possible about changes in your health. Between study visits, we ask that you call the clinic and this number (xxx) xxx-xxxx, if you are hospitalized overnight, have surgery, or break any bones.”

### 4.3 Incomplete Visits

Occasionally, participants who have not fasted before their baseline clinic visit will return for their oral glucose tolerance test at a later date (see section 4.1.2 in this chapter). Some participants may return to give a urine sample (see section 4.1); or may return for their CT, PFT, or DXA exam. Examiners are instructed to fill out the first page of the Baseline Clinic Visit Workbook to indicate that the clinic visit was incomplete or complete except for CT.

It is important to minimize the amount of time between the first and the second visit. It is not necessary to reweigh the participants who come in for a second clinic visit. Use the weight that is recorded on page 12 of the Baseline Clinic Visit Workbook for both the DXA and the PFT exams.

Very rarely, a measurement is not taken. For example, if the participant has a colostomy bag, the sagittal diameter cannot be measured. Whenever a measurement is not taken, write the reason next to the blank results field on the Baseline Clinic Visit Workbook and include a note in the progress notes in the participant's chart explaining why the measurement was not taken.

## 5. Alerts and Notifications

At the clinic visit, participants will receive a report that includes height, weight, blood pressure, PFT and DXA results (see Appendix 3). Other test results will follow as a final report except for alerts or abnormalities requiring earlier notification. The final report will be mailed to participants within eight weeks of the clinic visit. Alerts will be sent from the laboratory/reading centers within 1 to 2 days, and in most instances the participant and their medical provider should be contacted by the coordinator after consultation with the medical director. (Table 2 lists measures that have alert values.)

**Table 2**

**Health ABC Tests: Alert Values**

<b><u>Defined Values</u></b>	<b><u>Examiner Discretion</u></b>
Oral Glucose Tolerance Test	CES-D
SMAC/Chemistry	Teng Mini-Mental State Exam
Resting ECG	Long Distance Corridor Walk
Blood Pressure	(symptoms related to)
CT (determined by reading center)	
Pulmonary Function Test	

### 5.1 Oral Glucose Tolerance Test

Fasting blood glucose:	normal	≥ 50 mg/dl <115 mg/dl
	borderline	115-139 mg/dl
	elevated	≥ 140 mg/dl
	immediate alert	>350 mg/dl
		< 50 mg/dl
2-hour GTT:	normal	≥ 50 mg/dl <140 mg/dl

borderline	140-199 mg/dl
elevated	≥ 200 mg/dl
immediate alert	>500 mg/dl < 50 mg/dl

**Immediate alerts:** After consultation with the medical director, the clinic coordinator may notify the participant and participant's physician by telephone/fax if participant has granted permission to notify their physician. A follow-up letter is suggested. (See Appendix 5.)

**Elevated values:** After consultation with the medical director, the clinic coordinator may notify participant and participant's physician by fax/letter if participant has granted permission to notify their physician.

**Borderline or normal values:** Include in final reports to the participant and the participant's physician within 8 weeks of clinic visit. Present individual results and normal ranges as above.

## 5.2 Biochemical Tests

Cholesterol	normal	<200 mg/dl	<b>No alert value</b>
	borderline	200-239 mg/dl	
	elevated	>239 mg /dl	
Triglyceride	normal	60-250 mg/dl	<b>ALERT</b> >1000 mg/dl
HDL-C	normal	≥ 35 mg/dl	<b>No alert value</b>
LDL-C	normal	<130 mg/dl	<b>No alert value</b>
	borderline	130 -159 mg/dl	
	elevated	>159	
Fasting insulin	<b>We will not report values to participant or physician.</b>		
Creatinine	normal	0.7 - 1.5 mg/dl	<b>ALERT</b> > 3.0 mg/dl
Albumin	normal	3.0-5.5 mg/dl	<b>No alert value</b>
Alkaline phosphatase	normal	40-140 u/L	<b>ALERT</b> >350 u/L
Hg A <sub>1</sub> C	normal	4-6%	<b>No alert value</b>
		>7 may indicate	

elevated glucose  
levels

Handle alerts as above for OGTT. (See Appendix 6.)

### 5.3 Resting ECG

The Resting ECG procedure includes printing one tracing with the Marquette machine reading and one tracing without the reading. Any abnormal result as listed below would be overread by a physician before the participant leaves. The following statements would require clinic physician review:

- Heart rate <40 (bradycardia) or >135 (tachycardia)
- Atrial fibrillation or atrial flutter (new onset)
- Wolff-Parkinson-White (WPW) or ventricular pre-excitation
- Idioventricular rhythm
- Ventricular tachycardia
- Third degree or complete A-V block
- Any statement including reference to acute injury or acute ischemia

For any of the above alerts, the clinic physician will determine if immediate notification of participant's physician is required before the participant leaves the clinic. If necessary, the ECG will be faxed to the physician or sent with the participant to their physician.

A clinic physician will overread all other abnormal ECGs within one week of the participant's visit. The clinic physician will decide if the participant and the participant's physician should receive a report of the abnormal ECG before the final report is ready for distribution. A cover letter may be sent to the participant and the participant's physician (see Appendix 7).

The final report to the participant will include a statement that a copy of the ECG without interpretation has been sent to their physician. The final report to the participant's physician will include a copy of the ECG without an interpretation. If the participant does not have a physician, a copy of the ECG will be included in the participant report.

## 5.4 Blood Pressure

Immediate alert:  $\geq 210$  SBP or  $\geq 120$  DBP, refer to source of care immediately after discussion with the clinic physician.

Below are ranges of blood pressure measurements that require various schedules for referral to sources of care and ranges that are considered to be normal.

180-209 SBP or 110-119 DBP, refer to source of care within 1 week  
160-179 SBP or 100-109 DBP, refer to source of care within 1 month  
140-159 SBP or 90-99 DBP, confirm within two months  
130-139 SBP or 85-89 DBP, high normal, no referral required  
<130 SBP or < 85 DBP, normal, no referral required

Blood pressure measurements will be given to the participant at the time of the clinic visit. A printed form with the above referral information and levels, with blanks for recording the participant's values will be provided. The same information will be included in the final report to the participant and to the participant's physician (see Appendices 10 and 11).

## 5.5 Ankle-Arm Blood Pressure

No alerts.

The final report to the participant and the participant's physician will include the ankle/arm ratio with an explanation of the test as per CHS: For the participant report: "The ratio of ankle to arm systolic blood pressure is one measure of blood flow in the legs. The normal ratio is usually greater than 90%." For the physician report we would add: "This is a research application. If you are interested in more information about ankle-brachial index please read the following article:

"Newman AB, Siscovick DS, Manolio TA, Polak J, Fried LP, Borhani NO, Wolfson SK. Ankle-arm index as a marker of atherosclerosis in the Cardiovascular Health Study. Cardiovascular Health Study (CHS) Collaborative Research Group. *Circulation*, 1993 Sep, 88(3): 837-45."

## 5.6 DXA

Total Hip BMD will be reported to the participant at the time of the clinic visit. The value will be plotted on an appropriate sex and race-specific reference based upon normative data from NHANES III. Percent body fat from the DXA will also be reported without reference to a normal range. A report similar to the one attached will be included in the report given to the participant at the clinic visit. The same report would



be included in the final report for both the participant and the physician (see Appendix 3).

### **5.7 CT Scan**

No routine report will be given to the participant or their physician. Abnormalities will be reported by the reading center and, if needed, copies of the abnormal CT generated by the local CT facility will be provided to the clinic for forwarding to the participant's physician and the participant. Use Health ABC letter to report abnormalities. (See Appendix 8.)

### **5.8 Pulmonary Function Test**

Alert values: FEV1 < 1.0 liter or < 40% of predicted

Alert levels will be reported to the participant's physician by telephone/fax in a Health ABC letter. (See Appendix 9.) If the participant has no physician or has not given permission to release results, the participant will be notified by telephone.

Preliminary results will be given to the participant at the time of the measurement in the format suggested by Dr. Crapo. (See Appendix 3.) The results will also be included in the final reports to the participant and physician.

### **5.9 Teng Mini-Mental State Exam**

Scores from the Teng Mini-Mental State Exam will not be routinely reported to the participant or physician. However, the clinic nurse coordinator or physician/investigator may decide on an individual basis that the first year score should be discussed with the participant and reported to the participant's physician. (Some experts suggest that a score of 75 or below might prompt consideration of notification.)

If there is a significant decline in the score or a persistent low score at the second administration of the exam, the participant's physician may be notified. (Details of this notification and definitions of significant decline to be determined.)

### **5.10 CES-D**

Scores from the CES-D will not be routinely reported to the participant or physician.

Home interviewers will review responses to the CES-D portion of the questionnaire. Interviewers will discuss reported symptoms of depression with the participant to ensure that the participant is either receiving treatment or has information on sources of

care. Alternatively, the clinic nurse coordinator may discuss the symptoms of depression with the participant at the clinic visit. Notification of a high CES-D score will be sent to the participant's physician only if the participant requests it.

### **5.11 Long Distance Corridor Walk**

Results of the long distance corridor walk will not be given to the participant or the physician.

Any symptoms during the test will be evaluated by the clinic staff and investigators on a case by case basis, and referral to the participant's physician will be made if necessary.

### **5.12 Height and Weight**

Height and weight will be recorded on the form given to the participant at the time of the visit (see Appendix 3). These measurements will also be included in the final reports to the participant and their physician.

## **6. Clinic Safety**

### **6.1 Background and Rationale**

All life threatening emergencies that occur at the Health ABC clinic, such as acute myocardial infarction, should be referred for immediate evaluation at an acute care facility, with emergency measures taken in the clinic before departure. Minor emergencies, such as hypotension or fainting, receive treatment in the clinic. Although most emergencies are of even less severe nature, Health ABC Field Center Clinics are prepared for both types.

### **6.2 Major Emergencies**

When a serious life-threatening event occurs in the clinic setting, the primary concern of the clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. It is imperative that local emergency measures be activated; in most cases, this requires calling 911. Do not take the participant to the emergency room. Let the paramedics do that. At every clinic session a physician, physician assistant, or registered nurse with certification in basic life support is on duty and physically present. Needed life support procedures should be continued until emergency care arrives or the participant is transported to a hospital.

Each Health ABC clinic has specific emergency procedures which define:

1. Who is in charge during the emergency
2. Who administers treatments

3. Who is notified
4. What action clinic staff takes
5. Which reports are filed

Each clinic has, in addition to trained personnel and emergency equipment, posted in a conspicuous place, such as the reception area, the following:

- phone number of police station
- phone number of fire stations
- phone number of ambulance services

} **CALL 911 !**

In each participant's folder, the name and phone number of their physician or usual source of health care is available on a standard Health ABC form. The home and work telephone number of the next-of-kin are also listed.

All medical emergency situations should be coordinated by a physician when present in the clinic. In the physical absence of the latter, this role should be assumed by the charge nurse or senior physician assistant. When not physically present in clinic, they are within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the head nurse and/or senior physician assistant so that the name of the responsible physician is readily accessible. However, in no case should emergency referral and/or care be deferred while staff is attempting to locate a clinic doctor. All personnel should be trained to carry out their specific responsibility during an emergency. Retraining is conducted at least yearly, inclusive of any emergency drill.

All major emergencies should be documented, identifying the type of emergency and action taken. This report should be completed by the clinic coordinator and co-signed by a clinic physician and the Principal Investigator. These reports should be maintained in a central file at each field center and a copy of the report should be kept in the participant's chart.

### **6.3 Minor Emergencies**

The most common minor emergency is simple syncope (fainting) and near syncope. These events may occur during venipuncture or the pulmonary function test. Management of simple syncope or near syncope is the same whether associated with drawing blood or performing the pulmonary function test.

In any situation in which syncope is likely, such as during venipuncture, staff should verify that the participant does not look or feel faint. When the participant looks faint or feels faint the following steps should be implemented:

1. Have the person remain in the chair and sit with their head between their knees or lie down.
2. Crush an ampule of smelling salts and wave under the participant's nose for a few seconds. DO NOT place ampule directly under the nose.
3. Provide the participant with a basin and a towel when they feel nauseous.
4. Check blood pressure and pulse.
5. Have the participant stay in the chair until they feel better and their color returns. Re-check blood pressure and pulse.

If the participant continues to feel sick, recline the chair, place a cold, wet towel on the back of the person's neck, and notify the clinic nurse coordinator. When a participant faints, they should be cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house physician or nurse to assist the participant. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the participant is breathing. When life support measures are needed, the measures outlined in the above sections are followed.

#### **6.4 Emergency Equipment**

A basic first aid kit is maintained at each field center. The kit contains a reference guide of its contents, and is checked every six months and immediately after each use. At each Field Center, the study coordinator identifies the person responsible for this task.

#### **6.5 Emergency Plans in Case of Fire**

1. Notify the emergency management system (911) to report the fire.
2. Close all windows and doors.
3. Escort all participants to the nearest fire exit and assemble a safe distance from the building.
4. Alert the clinic coordinator and the building supervisor of the emergency situation.

## APPENDIX 1



HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
H <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

## YEAR 2 CLINIC VISIT WORKBOOK

Time of arrival:

 : 

Time of departure:

 : 

## YEAR 2 CLINIC VISIT PROCEDURE CHECKLIST

	Page Numbers	Please check if done		Comments
1. Medication Inventory Update	2	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
2. Weight	7	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
3. Radial Pulse, Respiratory Rate & Temperature	7	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
4. Blood Pressure	8	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
5. Food Frequency Questionnaire	9	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
6. Grip Strength	17	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
7. 20-meter Walk	18	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
8. Long Distance Corridor Walk	19	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
9. Ultrasound	24	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
10. Bone Density Scan (DXA)	26	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
11. Periodontal Eligibility Assessment	28	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
12. Dental Examination	31	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
13. Isokinetic Strength (Kin-Com)	32	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
14. Joint (OA) Evaluation	35	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
15. Knee X-ray Tracking	43	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable
16. Knee MRI Eligibility and Tracking	44	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable
17. Energy Expenditure (Visit 1)	46	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable
18. Phlebotomy	48	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
19. Laboratory Processing	49	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
20. Was the Year 2 Questionnaire administered?		<input type="checkbox"/> Yes	<input type="checkbox"/> No	

**Memphis Only:**Would you like us to send a copy of your test results to your doctor? ☐ Yes ☐ No

64991

Page Link #

♦Page 1♦

Version 1.1, 7/30/98



## APPENDIX 2



## BASELINE CLINIC VISIT WORKBOOK

HCFA Screening ID #	HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
<div><div>0</div><div>1</div><div>2</div><div>3</div><div>4</div><div>5</div><div>6</div><div>7</div><div>8</div><div>9</div></div> <div><div><div></div><div></div><div></div><div></div><div></div></div><div><div></div><div></div><div></div><div></div><div></div></div><div><div></div><div></div><div></div><div></div><div></div></div><div><div></div><div></div><div></div><div></div><div></div></div><div><div></div><div></div><div></div><div></div><div></div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>Month / Day / Year</div>	<div><div></div><div></div><div></div><div></div><div></div></div>

**Examiner Note:** Write the HCFA Screening ID # in the boxes and fill in the circles below that correspond to these numbers. The circles are the scannable portions of this field, so it is essential that they are filled in.

Time of arrival:  :

Time of departure:  :

What is the status of the clinic visit?

- ☐ Clinic visit completed
- ☐ Clinic visit completed **except** for CT
- ☐ Incomplete visit

**Memphis Only:**

Would you like us to send a copy of your test results to your doctor? ☐ Yes ☐ No

Page Link #

♦Page 1♦

Version 1.2a, 9/16/97



APPENDIX 3  
page 1 of 6**Health ABC Examination Results Form**

Participant Name: \_\_\_\_\_  
(Please Print)

Date of Clinic Visit: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

**Blood Pressure:**

Measurement 1 \_\_\_\_/\_\_\_\_ mm Hg

Measurement 2 \_\_\_\_/\_\_\_\_ mm Hg

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends for you:

(Check appropriate box.)

- ☐ Recheck blood pressure within 1 year
- ☐ Recheck blood pressure within 2 months
- ☐ See your doctor in 1 month
- ☐ See your doctor in 1 week
- ☐ See your doctor immediately

If you have any specific questions about your blood pressure, please consult your doctor.

Standing Height: \_\_\_\_\_  
(feet and inches)

Weight: \_\_\_\_\_  
(pounds)

Health ABC Examiner Name: \_\_\_\_\_  
(Please Print)

Health ABC Staff ID #: \_\_\_\_\_



APPENDIX 3  
page 2 of 6**Pulmonary Function Report**

Name: \_\_\_\_\_

Date: \_\_\_\_\_

A preliminary report of your lung function is shown below. A final report will be sent to you after these results have been analyzed. The report below is not a final report.

\_\_\_\_\_ Test was not performed or lung function could not be determined accurately.

## Results:

Lung Function Test	Your Value	Usual Normal Range
FVC	_____ of Predicted	80% and greater
FEV <sub>1</sub>	_____ of Predicted	80% and greater
FEV <sub>1</sub> / FVC	_____	65% and greater

FVC is the total amount of air you blew out of your lungs. FEV<sub>1</sub> is the amount of air you were able to blow out in the first second. FEV<sub>1</sub> / FVC is the ratio of the other two volumes.

\_\_\_\_\_ If the values are within the normal range or above, your lung function is normal.

\_\_\_\_\_ If these values are below the usual range, your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range.

\_\_\_\_\_ If either FVC or FEV<sub>1</sub> are less than 50% of your predicted normal value, or if your FEV<sub>1</sub> / FVC ratio is less than 50%, your function is substantially reduced. If you and your physician were unaware of this, you should see them soon for evaluation.

## Health ABC Bone Density Results

Name: \_\_\_\_\_

Date of Scan: \_\_\_\_\_

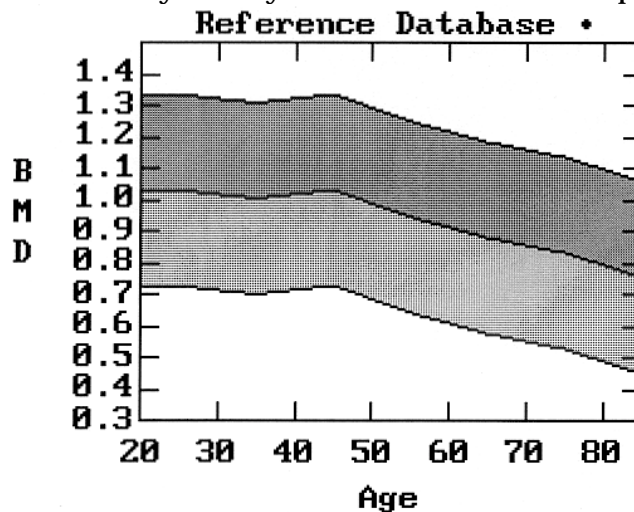
As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range

for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.

Total hip BMD: \_\_\_\_\_ g/cm<sup>2</sup>

% body fat \_\_\_\_\_.

(Black Female)

Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

## Health ABC Bone Density Results

Name: \_\_\_\_\_

Date of Scan: \_\_\_\_\_

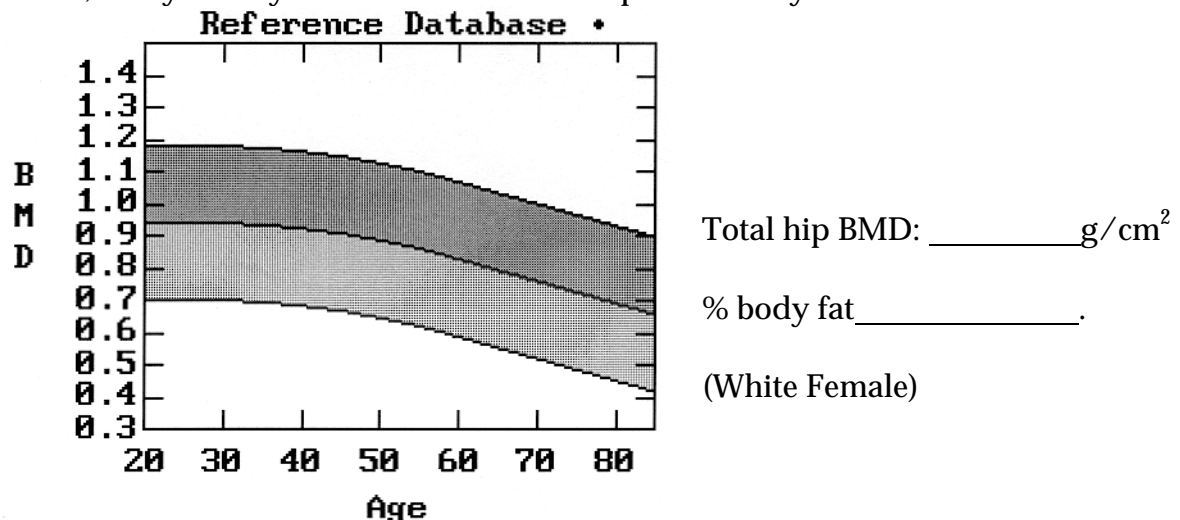
As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range

for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.



Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

## Health ABC Bone Density Results

Name: \_\_\_\_\_

Date of Scan: \_\_\_\_\_

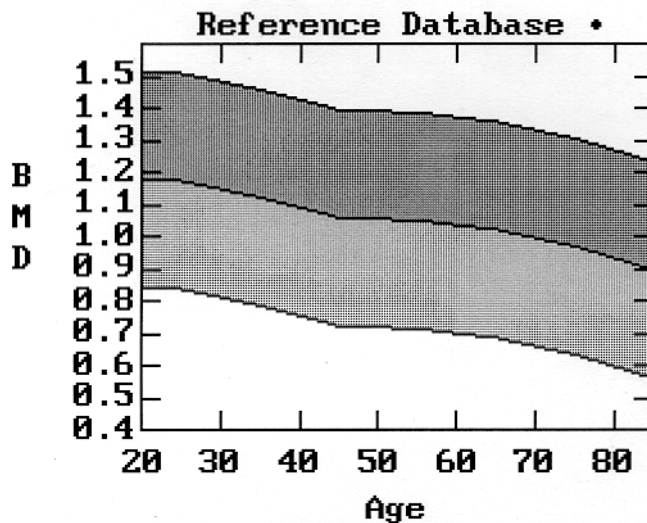
As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range

for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.

Total hip BMD: \_\_\_\_\_g/cm<sup>2</sup>

% body fat \_\_\_\_\_.

(Black Male)

Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

## Health ABC Bone Density Results

Name: \_\_\_\_\_

Date of Scan: \_\_\_\_\_

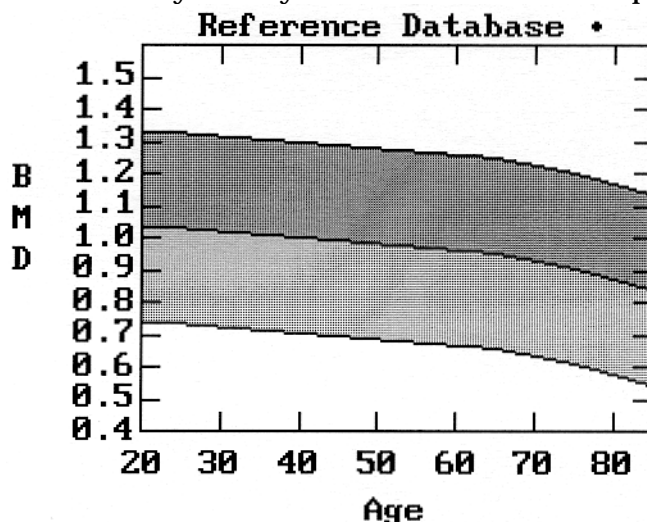
As part of the Health ABC Study, we measure the bone mineral density (BMD) of your hip and whole body using a technique called dual energy x-ray absorptiometry. Bone densitometry provides a measurement of the calcium content of your bones. Individuals with low bone density have an increased risk of fractures. The machine also reports the proportion of your body that is fat (or percent body fat). The shaded area of this graph represents the range

for someone your age of normal bone mineral density values. As you can see, bone density declines with age, and this decline begins at around age 30. The bone density of your hip is indicated by the "X" and is considered within normal limits for your specific age if it lies anywhere in the shaded region. Above the solid middle line is considered high-normal; below the solid middle line is considered low-normal. The BMD of your hip should be similar to the BMD in your skeleton in general. A low BMD may predict fracture risk both in the hip and in other parts of the skeleton.

To decrease the risk of osteoporotic fractures:

- Take precautions to avoid falling
- Stop smoking
- Avoid excess alcohol consumption
- Ensure an adequate daily supply of calcium and Vitamin D
- Engage in regular physical activity, especially weight-bearing exercise (i.e. walking, aerobics)

Please share this result with your physician. If you have osteoporosis, treatments are available, and you may want to discuss these options with your doctor.

Total hip BMD: \_\_\_\_\_ g/cm<sup>2</sup>

% body fat \_\_\_\_\_.

(White Male)

Note: This procedure determines bone density and does not diagnose cancer, arthritis, rheumatism, bursitis or torn ligaments, tendons and cartilage.

**APPENDIX 4:  
HEALTH ABC APPOINTMENT REMINDER****JUST A REMINDER . . .**

Your Health ABC appointment is scheduled for:

---

(Date/Time)

Please remember to:

- Fast for 12 hours prior to your visit (no eating or drinking, except water and prescription medications.)
- Drink plenty of water.
- Please DO take any prescription medication you normally take the morning of your visit, except:

For those participants with diabetes: DO NOT take your insulin or hypoglycemic medications the morning of your clinic visit. You will take these medications in the clinic after the blood draw. Please be sure to bring these with you.

- Bring ALL medications (in their containers) with you (including prescription, non-prescription medications, insulin, vitamins) that you have used in the two weeks prior to your clinic visit.
- Refrain from smoking or vigorous physical activity for 12 hours prior to your visit.
- Please: No jewelry, no hair pieces, no girdles or pantyhose.
- Bring reading glasses and/or hearing aids with you.
- Wear comfortable shoes for walking.
- A urine specimen will be collected shortly after you arrive in the clinic.

If you need to reschedule, please call \_\_\_\_\_. Tell the operator you wish to reschedule your Health ABC appointment.

**APPENDIX 5:  
OGTT ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.  
5845 Centre Avenue  
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient \_\_\_\_\_ at the Health ABC Clinic. [A fasting and 2-hour OGTT glucose were obtained and the results of the fasting glucose are 76 mg/dl, and the 2-hour glucose was 40 mg/dl. (Alert values are <50 mg/dl or >500 mg/dl.)] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at \_\_\_\_\_. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH  
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd  
Coordinator of Clinical Studies

/sa



**APPENDIX 6:  
LAB ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.  
5845 Centre Avenue  
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient \_\_\_\_\_ at the Health ABC Clinic. [A serum creatinine of 5.2 mg/dl and a phosphatase of 360 u/L were obtained. (Alert values are serum creatinine > 3.0 mg/dl and alkaline phosphatase > 35 u/L.)] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at \_\_\_\_\_. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH  
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd  
Coordinator of Clinical Studies

/sa

**APPENDIX 7:  
ECG ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Charles Cutler, M.D.  
512 Hamilton Road  
Marion, PA 19066

Dear Dr. Cutler:

On June 1, 1997, we performed a surveillance visit on your patient \_\_\_\_\_ at the Health ABC Clinic. [An ECG was obtained and indicates the participant now has evidence of an abnormality. A copy of the tracing is enclosed.] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at \_\_\_\_\_. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH  
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd  
Coordinator of Clinical Studies

/sa

**APPENDIX 8:  
CT ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.  
5845 Centre Avenue  
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient \_\_\_\_\_ at the Health ABC Clinic. [A CT was obtained and indicates the participant now has evidence of an abnormality. A copy of the image is enclosed.] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at \_\_\_\_\_. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH  
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd  
Coordinator of Clinical Studies

/sa

**APPENDIX 9:  
PFT ALERT LETTER FOR PHYSICIAN**

March 13, 1997

Abe Friedman, M.D.  
5845 Centre Avenue  
Pittsburgh, PA 15213

Dear Dr. Friedman:

On June 1, 1997, we performed a surveillance visit on your patient \_\_\_\_\_ at the Health ABC Clinic. [A pulmonary function test was performed and indicates the participant now has evidence of an abnormality. (Alert values are: FEV1 <1.0 liter and 40% of predicted.) A copy of the pulmonary function report is enclosed.] We will send the remainder of the results when we receive them from the Health ABC Coordinating Center.

All tests were performed for research purposes only and will be used to describe the health status of men and women in their seventies who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at \_\_\_\_\_. Thank you for your support.

Sincerely,

Anne Newman, M.D., MPH  
Health ABC Principal Investigator

Marguerite Meyer, RN, MEd  
Coordinator of Clinical Studies

/sa